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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,466	04/26/2001	Hiroyasu Kokubo	35576/233803	8005

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,466	KOKUBO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,11,13-20 and 31-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,11,13-20 and 31-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
PATENT EXAMINER
TC-1600

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Pre-Appeal Brief Request, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 01/04/06 is acknowledged.

Upon further review and consideration, the previous Non-Final Office Action filed 07/28/05 has been withdrawn. The following are the new grounds of rejection:

Claims 6-9, 11, 13-20 and 31-47 are pending in this action. Claims 1-5, 10, 12 and 21-30 have previously been cancelled. Claims 6-9, 11, 13-20 and 31-47 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-9, 11, 13-17 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) in view of Dempski *et al.* (U.S. Pat. No. 3,409,570).

The instant invention is drawn to a solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of coating a solid preparation with a continuous film coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

Hampton *et al.* ('270) teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

The multiple characteristic tablet comprises different color sections, which includes a color demarcation line (22) extending traversely between the halves (14 & 18) of the core. The core (12) is preferably coated with a clear material (24). The coloring agents employed are conventional and any desired color combination could be employed (col. 3, lines 5-38).

A feature of the invention is to coat the bi-layer, two-colored tablet with a single coating of gelatin or a film-forming polymeric substance, which will simulate the appearance, and function of the gelatin capsule. Suitable film-forming materials include methylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, ethylcellulose, various derivatives of methacrylic acids and methacrylic acid esters, and cellulose acetate phthalate (col. 5, lines 37-49). The coating of the film-forming polymer may be applied in several ways, such as by using conventional coating pans. Spray guns or other suitable atomizing equipment may be introduced into the coating pans to provide spray patterns conducive to rapid and uniform coverage of the tablet bed. The coating material is sprayed until the tablets are uniformly coated to the desired thickness and desired appearance of the tablet (col. 5, line 59 – col. 6, line 15).

The examples at columns 7-9 demonstrate two-colored, bi-layered capsule-shaped tablets. For instance, Example 1 demonstrates a bi-layered capsule-shaped tablet made from two separate layers, which were compressed together on a tablet press to form a tablet with an appearance similar to a capsule's appearance.

The instant claims are drawn to a solid preparation coated with a multi-colored continuous film coating layer prepared by coating a solid preparation with a continuous film-coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

While Hampton *et al.* teach a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents, Hampton *et al.* do not teach 'exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration'.

Dempski *et al.* ('570) teach stabilization of dyes in a film coating material, whereby a colored pill or tablet is provided that retains its colorful appearance during prolonged exposure to sunlight or ultra-violet radiation. Dempski *et al.* teach stabilization of coloring agents and particularly, a dye containing film-coating material whose color intensity is not adversely effected by sunlight or ultra-violet light (UV light) (see reference column 1, lines 1-43). According to Dempski *et al.*, the incorporation of certain agents into a colorful film forming composition suitable for coating products, inhibits the fading of the color contained therein, when said film coating is exposed to sunlight or ultra-violet light. Stabilization can be achieved

by incorporating agents such as polyvinylpyrrolidone (PVP) or copolymers of vinylpyrrolidone, for example (col. 1, lines 44-56).

Dempski *et al.* also teach that to achieve market acceptance of certain products, it is sometimes desirable to color pills, tablets or other shaped cores and the like so as to enhance their physical appearance. This renders the product more acceptable for therapeutic administration. For the same reason, coloring matter must resist the effects of sunlight and ultraviolet radiation (col. 1, lines 25-38).

The examples at columns 3-5 demonstrate various tablet formulations, wherein the tablets were exposed to light sources. Example 1, at column 3 for instance, demonstrates preparation of a tablet whereby samples of a finished tablet were exposed to intense ultraviolet radiation from an ultraviolet lamp for 72 hours. Table 1 presents the results of samples that were exposed to the ultraviolet light and also presents results of samples that were protected from the UV exposure. The visually observable color characteristics are shown in the Table.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dye coating material stabilization methods, which comprise the step of exposing pills or tablets to sunlight or ultraviolet radiation taught by Dempski *et al.* within the multi-characteristic, bi-layered, two-color tablet of Hampton *et al.* if one would desire a color change effect observed in the tablet. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dempski *et al.* teach and recognize that visual effects are obtained in tablets upon exposure with sunlight or ultraviolet radiation, such as fading and discoloration of tablet, as well as differences in the levels of color intensity of tablets. The

expected result would be an enhanced, multi-colored continuous coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer.

A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents. The prior art also demonstrates the teaching of irradiating pills or tablets, which result in distinct coloring along the length of the tablet or pill. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. The prior art recognizes and teaches a tablet that is multi-colored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet and teaches the concept that the exposure of tablets to radiation, results in fading or discoloration of tablets.

Claims 18-20 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) in view of Dempski *et al.* (U.S. Pat. No. 3,409,570) as applied to claims 6-9, 11, 13-17 and 31-44 above, and further in view of Hoover *et al.* (US Pat. No. 5,464,631).

Hampton *et al.* ('270), as discussed above, teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear

coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

Hampton *et al.* teach color demarcation lines on the tablet. Hampton *et al.* do not teach the inclusion of patterns comprising logos, bar codes or letters.

Hoover *et al.* ('631) teach a two-colored medicament dosage form having embossed or debossed letters, logos, symbols and the like on the surface of the dosage form (see reference column 4, lines 37-44).

It would have been obvious to use the combined teachings of Hoover *et al.*, who teaches a two-colored medicament comprising embossed letters, logos, symbols and the like, within the formulation of Hampton *et al.* who teaches a two-colored tablet with distinct color demarcations because Hoover *et al.* teach that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form. The expected result would be a distinct, visually improved solid dosage form for easier brand recognition.

Response to Arguments

Applicant's arguments filed 01/04/06 have been fully considered and were found to be persuasive. Accordingly, the previous Non-Final Office Action filed 07/28/05 has been withdrawn. This Office Action contains new grounds of rejection:

Firstly, Applicant argued in regards to the 35 U.S.C. §103(a) rejection of claims 6-9, 11, 13-17 and 31-44 over Hampton et al. (US 5,089,270) stating, "Hampton describes a multi-

colored tablet that is coated with a clear coating. The multi-coloration is achieved by combining a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material. The two-colored tablet is subsequently coated with a clear gelatin layer through which the color components are visible. The gelatin layer is clear and is not multi-colored. The two-color sections comprise the core of the tablet and are not part of the coating. Hampton fails to disclose each and every limitation of claims 31 and 33. Hampton describes a tablet wherein the colored components are not in the coating layer at all, but rather comprise two distinct portions in the interior of the tablet that are compressed together. Hampton does not disclose a solid preparation having a continuous multi-colored film coating layer. Furthermore, there is no teaching or suggestion in Hampton of how to prepare a continuous coating having different colorations. In fact, Hampton's specific description of a clear coating layer teaches away from the recited different colorations in the multi-colored coating layer of the claimed invention. There is no disclosure or suggestion in the prior art to provide any motivation to modify Hampton's clear coating layer and to provide differences in coloration in the coating layer. Hampton clearly teaches that the differences in coloration arise from the core not the outer coating. There is also no teaching in Hampton of how to modify the coloration of the outer coating. Modifying Hampton's tablet to have different colorations in the coating would render Hampton's tablet unsatisfactory for its intended purpose. The claimed invention is patentable over Hampton because Hampton does not disclose or suggest a structure wherein the coating layer has different colorations".

Applicant's arguments have been fully considered and were found persuasive. Accordingly, the 35 U.S.C. 103(a) rejection of Hampton alone has been withdrawn. However, the Office Action now presents the 35 U.S.C. 103(a) rejection of claims 6-9, 11, 13-17 and 31-44 over Hampton in view of Dempski et al. (USPN 3,409,570). While Hampton does not teach a two-colored coating layer, whereby first and second portions of the tablet are exposed to radiation, Dempski et al. explicitly teach dye stabilization coatings whereby the pills or tablets are exposed to radiation, such as ultraviolet light or sunlight to provide for distinct coloration along the body of the tablet. The Dempski reference demonstrates the teaching that various effects, such as fading and discoloration are obtained upon exposure of tablets to radiation, such as sunlight or ultraviolet light. Therefore, the reference teaches the same concept of providing for multicolored continuous coating layers on solid preparations, as desired by Applicant.

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 18-20 and 45-47 over Hampton ('270) in view of Hoover (US 5,464,631) stating, "Similar to Hampton, Hoover does not disclose or suggest a solid preparation having a continuous multi-colored film coating layer. Moreover, the claimed invention describes a coating wherein the pattern of two or more different colors is part of the continuous coating. In contrast, Hoover describes a caplet wherein the logos and the like are on the surface of the caplet. Thus, Hoover fails to disclose or suggest a solid preparation where 'embossed or debossed letters, logos, symbols and the like' are an actual part of the coating. In contrast, Hoover describes a caplet wherein the logos and the like are on the surface of the caplet."

Applicant's arguments have been thoroughly considered, but were not found to be persuasive. Applicant employs patterns, such as logos, letters and bar codes for easier

identification and recognition of tablets. The reference of Hoover et al. was relied upon for their teaching that it is known in the art to employ patterns that include logos, bar codes or letters in multi-colored tablet formulations. The Hoover reference teaches that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form (see Hoover col. 4, lines 37-43). While the caplet of Hoover provides for logos and the like on the surface of the caplet, the reference demonstrates the same purpose as desired by Applicant, which is to provide easier recognition as well as an aesthetically pleasing appearance of tablets. Thus, Applicant's arguments were not rendered persuasive.

Given the teachings of the prior art delineated above, it is the position of the Examiner that the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh Humera N. Sheikh TC-1600

Patent Examiner

Art Unit 1615

April 14, 2006

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